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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/382,779 07/03/00 POMPEJUS

W 48715

KEIL & WEINKAUF
1101 CONNECTICUT AVENUE NW
WASHINGTON DC 20036

HM12/0824

EXAMINER

GANSHEROFF, L

ART UNIT	PAPER NUMBER
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1636

DATE MAILED:

08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/582,779

Applicant(s)

POMPEJUS ET AL.

Examiner

Lisa Gansheroff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

DETAILED ACTION

Pending claims: 1-15.

This action is in response to: Amendment filed 03 August 2001 (Paper No. 11).

Specification

Applicants' amendments to the specification have been entered. Several typographical errors, as follow, were corrected by the Examiner by comparing with the original specification. In the amendment to page 12, lines 39-46: in the first line of the amended section, "gnomic" was corrected to "genomic"; in the third line of the amended section "FAN" was corrected to "DNA". Additionally, in the amendment to page 13, lines 35-43: in the second line of the amended section, "PCT" was corrected to "PCR"; in the fifth line of the amended section "gnomic" was corrected to "genomic"; in the sixth line of the amended section "autotrophic" was corrected to "auxotrophic".

The Brief Description of the Drawing, submitted with the Amendment, has been inserted into the specification on page 3 just before the last paragraph on the page.

Claim Objections

Claim 10 as amended is objected to because of the following informalities: there appears to be an unintentional duplication of several lines of type. It is suggested that Applicants amend the claim by deleting the section from (and including) the word "which" on the fifth line to (and including) the word "microorganism" on the eighth line. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not recite that the gene or amino acid sequence has been isolated from or otherwise altered from its naturally-occurring form in nature in an *Ashbya gossypii* cell. See MPEP 706.03(a)

In response to this rejection, Applicants argue that according to the specification page 4, lines 24-29, the claimed genes are in fact isolated from organisms. This argument has been fully considered but is not persuasive because the cited section of the specification does not say that the claimed genes are isolated; this section only says that "it is possible" for them to be isolated (see lines 24-25). Further, the claims are worded to encompass subject matter that is not isolated from or otherwise altered from its naturally-occurring form in nature (in any cell). Thus, the rejection stands.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the phrase "derive from". This phrase renders the claims indefinite because the nature and number of derivative steps are not defined, and thus the metes and bounds of the claims are not known.

In response to this rejection, Applicants argue that the phrase "derive from", based on page 4, lines 24-29 of the disclosure, refers to the isolation of SEQ ID NO: or its homologs from *Ashbya gossypii*. This argument has been fully considered but is not persuasive because other sections of page 4 of the specification define derivatives as promoter variants and so forth (lines 9-22). Thus, the rejection stands. It is suggested that the phrase "derive from" be replaced with "isolated from" since this would reflect Applicants' intent according to the above argument.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 stand rejected, and claims 14-15 (as amended) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-15 are drawn to a genus of orotidine-5'-phosphate decarboxylase genes having the sequence of SEQ ID NO:1 or its homologs which have at least 80% homology, or amino acid

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sequences encoded by the genes. All of the claims except claim 2 also encompass "homologs" from any organism. The specification only describes SEQ ID NO:1, which is the orotidine-5'-phosphate decarboxylase gene from *Ashbya gossypii*. In a search of the prior art, the Examiner was unable to find a gene having at least 80% homology with SEQ ID NO:1. Thus, only one species of the claimed genus appears to have been known at the time of the invention; no genes having at least 80% homology to SEQ ID NO:1 were found in the prior art. Further, based on the wording of claim 4, which specifically recites an amino-acid sequence which comprises an enzymatically active protein, it appears that the other claims lack a correlation between structure and function. That is, the homologs of the other claims apparently need not encode enzymatically active proteins. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, including genes encoding both active and non-active proteins, and also including genes from any organism, SEQ ID NO:1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

In response to this rejection, Applicants argue that homologs are disclosed in the specification on pages 3 and 4. Applicants also argue that the fact that homologs of SEQ ID NO:1 could not be found in the prior art shows that the claims are novel, and that "a particular sequence easily can be modified by genetic engineering to yield homologs without rendering the activity of the corresponding protein". These arguments have been fully considered but are not persuasive because of the following. First, the specification does not describe homologs; that is the specification does not give the sequence (structure) of any "homologs" except for mutants

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that do not retain activity. The specification on pages 3-4 merely states that the term homologs encompasses allelic variants with at least 80% (or other percent) homology, variants that retain or do not retain activity, fungal or plant homologs, promoter variants, and so forth. However, the specification does not present a description of what the sequence of a promoter variant (that increased or did not impair the promoter activity, see page 4) would look like. The specification does not describe the sequence of any variants with 80% homology that retain activity. The specification does not describe the sequence of any homologs with 80% homology to SEQ ID NO:1 from any fungal organisms aside from *Ashbya gossypii*, and does not does not describe the sequence of any homologs with 80% homology to SEQ ID NO:1 from any plants. There might not even be any such homologs with 80% homology from other fungi and plants, and even if there are, Applicants were not in possession of them. Further, the fact that SEQ ID NO:1 is novel over the prior art does not mean that the specification has a written description of a representative number of "homologs" encompassed by the instant claims. Thus, the rejection stands.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Gansheroff whose telephone number is (703) 605-1203. The examiner can normally be reached 9 AM - 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Dianiece Jacobs whose telephone number is (703) 305-3388 or to the receptionist whose telephone number is (703) 308-0196.

LG
August 16, 2001



JAMES KETTER
PRIMARY EXAMINER